K021635

OCT 28 2002

510(k) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

510 (k) SUMMARY
FOR
Karats Multipurpose Solution

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person:Steven Dowdley
Telephone No. 678-415-3897

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: Karats Multipurpose Solution

3. **Predicate Devices**

SOLOCare Plus Multipurpose Solution

4. Description of the Devices

Karats Multi-Purpose Solution is a sterile aqueous solution containing sorbitol, tromethamine, pluronic F127, sodium phosphate dihydrogren, edetate disodium dihydrate and preserved with polyhexanide 0.0001%.

5. **Indications for Use**

Karats Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

A series of preclinical and clinical studies were completed to demonstrate the substantial equivalence of Karats Multi-Purpose Solution to the predicate device(s). All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and biocompatible, and is comparable to other currently marketed soft contact lens solutions. Results from all tests demonstrate the substantial equivalence to previously FDA approved predicate device.

Lens Compatibility Data:

There was no significant difference between Karats Multi-Purpose Solution and the control solution, with respect to optical and physical changes in the measured properties of the lenses.

Cytotoxicity

A series of cytotoxicity studies were conducted to demonstrate the safety of Karats Multi-Purpose Solution. Results of the testing demonstrated that Karats Multi-Purpose Solution is non-cytotoxic and is a non-irritant.

Microbiological

Microbiological studies were conducted to demonstrate the microbial efficacy Karats Multi-Purpose Solution. The studies evaluated the performance of the product under a

pre-rinse/ no rub regimen. The studies demonstrated that Karats Multi-Purpose Solution meets the stand-alone criteria with organic load for disinfection and meets the regimen test criteria.

Clinical Testing
A clinical study was conducted to support the substantial equivalency of Karats Multipurpose to currently marketed SOLO-Care Plus Multipurpose Solution.

Karat 257 versus SOLOCare Plus
Karats 257 is a new multipurpose contact lens care solution designed to help increase contact lens comfort and provide a better lens wear experience. The primary objective was to evaluate safety, efficacy and preference between Karats Multipurpose Solution using a no rub/no rinse regimen compared to SOLO-care ® Plus multipurpose solution. The trial was planned as a one-month prospective, randomized, double masked trial consisting of baseline, two-week, and final one-month visits. Subjects compared the test and control products on a contra-lateral basis and were randomized into two treatment groups according to which eye is to use the test and which eye is to use the control solutions.

Contact lens visual acuity was approximately similar between the eyes with 69% of the Karats 257 eyes and 75% of the SOLO-care ® Plus eyes having a final VA same or better than the baseline. Symptoms were equivalent and slit lamp findings were generally of a low grade (<2). There was a trend for less corneal staining with Karats 257.

Karats 257 had fewer lens deposits at 1-month, a slightly longer period of hours of comfortable wear and a trend for less corneal staining. Subjectively Karats was rated higher for overall comfort and preferred for lens awareness at the 1-month visit. There was no difference in image analysis. There were a few more reports of mild burning on insertion with Karats 257. Overall comfort was approximately 0.5 of a grade higher, and lens awareness was also more favorably scored with the Karats 257 treated lens and these were statistically significant. Approximately twice as many SOLO-care ® treated lenses were reported with slight, moderate, or severe deposits at the one-month visit as compared to Karats 257 treated lenses, although there was no difference at the two-week visit. Approximately an additional quarter hour of comfortable wear was reported for the Karats 257 eye at the one-month visit that was a statistically significant difference.

The results of the study showed that Karats Multipurpose Solution is substantial equivalence to SOLO-care ® Plus.

7. Substantial Equivalence

The date provided in this 510(k) submission concludes that Karats Multipurpose Solution is substantially equivalent to SOLO-Care Plus Multipurpose Solution for cleaning, rinsing, chemical (not heat) disinfecting, protein removal, and storing soft (hydrophilic) contact lenses (replaced in 30 days or less) as recommended by your eye care practitioner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2002

CIBA Vision Corporation
C/O Steven Dowdley, RAC
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K021635
Trade/Device Name: Karats Multipurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: August 9, 2002
Received: August 12, 2002

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: **K021635**

Device Name: Karats Multi-Purpose Solution

Indications for Use:
Karats MPS is indicated for cleaning, rinsing, chemical (not heat) disinfecting, protein removal and storing soft (hydrophilic) lenses as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☒

Karen Warburton

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021635